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US Environmental Protection Agency
Chemical-Right-To-Know Program
P.O. Box 1473
Merrifield, VA 22116
Attention: Mr. Richard Hefter

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OPPT/CBIC

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Re: Response to Comments on HPV Test Plan

Dear Mr. Hefter:

In keeping with the HMMM Coalition's commitment to the EPA High production Volume Voluntary program, we have previously submitted a test plan and robust summaries for CAS# 3089-11-0, Hexamethoxymethylmelamine. We have subsequently reviewed EPA's comments and comments from the public regarding our submission, including input from People for the Ethical Treatment of Animals (PETA) and Environmental Defense. We enclose a revised test plan modified in response to these comments.

In response to EPA's comments, we have added the additional study details to some of the robust summaries, including more detailed compositional information for the test material. We have also made clarifying changes in the text of the test plan regarding the descriptions of HMMM in its monomeric and polymeric forms. The test plan noted that monomeric HMMM is typically present at 28-50% in commercial products. In response to EPA's inquiry regarding the balance of the mixture, the non-HMMM materials present in the commercial mixture are largely dimers or higher oligomers (about 33-47%). Some HMMM derivatives may also be present, leaving a smaller percentage of less methylated/ methylolated species present. In any event, the testing using a commercial product will represent the toxicity of the mixture.

With respect to the proposed testing, the HMMM Coalition agrees with EPA's recommendations and intends to conduct the following additional studies:

- Melting Point – per OECD 102
- Water Solubility – per OECD 105
- Hydrolysis – per OECD 111
- Ready Biodegradation – per OECD 301B

As proposed in the plan, the HMMM Coalition will also conduct testing for Acute Toxicity to Green Algae per OECD 201 and Combined Repeated Dose Oral Study With Reproduction/Developmental Toxicity Screen using OECD 422.

May 29, 2003

As the PETA comments note, it is reasonable to expect HMMM to have very low toxicity in light of the available data. Commenting on the proposed plan to conduct a combined reproductive/developmental study, PETA notes that to the extent any toxicity is exhibited, it is likely due to formaldehyde. However, formaldehyde would not be expected to lead to reproductive or developmental effects. See Collins, et al., A Review of Adverse Pregnancy Outcomes and Formaldehyde Exposure in Human and Animal Studies, *Regulatory Tox. & Pharmac.* 34:17 (2001); Organisation for Economic Cooperation and Development, SIDS Initial Assessment Profile for Formaldehyde (2002). PETA acknowledges that animal studies have not generally supported the possibility of reproductive or developmental toxicity from formaldehyde, and we refer PETA to the thorough review of the humans studies by Collins, et al. Based on the wealth of available evidence in both animals and humans, we do not believe that PETA's suggestion that we conduct human epidemiology studies covering reproductive effects and developmental toxicity is warranted.

With regard to PETA's suggestion that we use an *in vitro* embryotoxicity test for HMMM, we understand that EPA will not accept such a test for the HPV program. There is no OECD method for such a study, nor have we been able to locate a commercial laboratory that conducts such testing under GLP guidelines.

The Environmental Defense (ED) comments also noted that the data presented in the test plan provide reasonable assurance that HMMM has low toxicity. ED supports the proposed combined repro/developmental study. ED concludes that the test plan overall is "very acceptable," provides a good description of available data, and proposes appropriate limited further testing.

We appreciate the careful review provided by all of the commenters. We attach the revised test plan and robust summaries in hard copy with the mailed copy of this letter, and in .pdf electronic format via e-mail.

Finally, please update your records to reflect that Solutia's interests in HMMM have now been assumed by UCB. Thank you very much.

Respectfully submitted,

Katherine L. Rhyne
King & Spalding
Counsel to the HMMM Coalition
Administrative Contact

cc: Dr. Randy Deskin
Cytotec Industries
Technical Contact